

K000575

510(k) Summary

Name of Sponsor: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) Contact: Marcia J. Arentz
Senior Regulatory Associate
Phone: (219) 371-4944
FAX: (219) 371-4940

Trade Name: Global™ Advantage® Extended Humeral Head

Common Name: Shoulder prosthesis, humeral head

Classification: When used as a hemi-shoulder, it is a **Class II** device per 21 CFR §888.3690
When used as a total shoulder, it is a **Class III** device per 21 CFR §888.3660

Device Product Code: Code: **87HSD** Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (Class II).
Code: **87 KWS** Prosthesis, Shoulder, Semi-constrained, Metal/Polymer Cemented (Class III).

Substantially Equivalent Device: Global Advantage Humeral Head K984541

Device Description: The Global Advantage Extended Humeral Head is a modified Global Advantage Humeral Head. The humeral heads mount on a humeral stem. The components are modular in that they employ a morse-type taper lock system, the modular head having the male taper and the stem with the female taper. The humeral heads are manufactured from cobalt chromium molybdenum alloy.

Intended use: The Global Advantage Extended Humeral Head, in combination with the Global Shoulder Advantage humeral stem, is intended for use in total or hemi-arthroplasty.

Indications for use: Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;

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2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;

3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

Substantial equivalence:

The Global Advantage Extended Humeral Head is substantially equivalent to the Global Advantage Humeral Head cleared in K984541. Both humeral heads have identical locking tapers, are semi-spherical in design, come in similar head sizes and are manufactured from the same materials with the same surface finishes. The only difference between the two heads is the addition of a flange to better accommodate the rotator cuff tear arthropathy patient.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Ms. Marcia J. Arentz
Senior Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K000575

Trade Name: Global™ Advantage® Extended Humeral Head

Regulatory Class: III

Product Codes KWS and HSD

Dated: February 21, 2000

Received: February 22, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Neil R. Dillard III", with a small "for" written below it.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000575

Device Name: **Global™ Advantage® Extended Head**

Indications for Use:

Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).
4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

Only the titanium alloy humeral stem components and the cobalt-chrome alloy humeral stem components, which are marketed under either the **Global Shoulder** or **Global Advantage Shoulder** name, are intended for press-fit or cemented fixation. The glenoid components are for cemented use only.

CAUTION:

The cobalt-chrome alloy humeral components, which are marketed under the **HRP Shoulder** name and **all glenoid** components are for **CEMENTED USE ONLY**.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

MDR for JSD

K000575

Prescription Use ☒
(Per 21 CFR 801.109)

OR Over-The-Counter Use

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